Time Critical Diagnosis—Stroke and STEMI System Implementation

DRAFT Highlights-Meeting Five, February, 10 2009

ATTENDEES:

Dr. Samar Muzaffar, Department of Health and Senior Services (DHSS); Lisa Archer, Northeast Regional Medical Center; Brenda Arndt, DHSS; Kristi Baden, Boone Hospital Center; Dave Barringhaus, Physio-Control; Jack Bates, Air Evac Lifeteam; Carol Beal, St. John's Regional Health Center; Anita Berwanger, DHSS; Linda Black, Pike Memorial County Hospital; Barbara Brendel, DHSS; Linda Brown, Southeast Missouri Hospital; Terry Buddemeyer, Washington Area Ambulance District; Jo-Ann Burns, Barnes-Jewish Hospital; Chris Byrd, Southeast Missouri Hospital; Dr. W. Stephen Casady, Putnam County Hospital; Donna Cash, North Kansas City Hospital; Dr. Douglas Char, Washington University School of Medicine; Doug Clark, Herman Area EMS; Karen Connell, DHSS; Adrianne Courter, I-70 Medical Center; Rich Dandridge, Warren County Ambulance District; Susan Davis, St. John's Mercy Medical Center; Liz Deken, American Heart Association; Marcia Dial, Scotland County Memorial Hospital; Lisa Donnelly, St. Luke's Hospital; Mary Jo Draper, The Vandiver Group; Joan Eberhardt, Missouri Emergency Nurses Association; Johanna Echols, Missouri State Medical Association; Ellen Ehrhardt, DHSS; Rhonda Evans, Community Hospital Association; Kelly Ferrara, The Vandiver Group; Cindy Feutz, University of Missouri Hospital and Clinics; Michael French, Missouri Rural Health Association; Nick Frey, Stinson, Morrison & Hecker; Shirley Gastler, DHSS; Dolly Giles, Pike County Memorial Hospital; Dale Green, PRN Healthcare Consultants; Gina Gregg, Research Medical Center; Paul Guptill, Missouri Hospital Association; Dr. David Gustafson, Independence; Robin Hamann, American Heart Association; Kathleen Henderson, St. Joseph Medical Center; Michael Hicks, Mid-American Regional Council; Linda Hill, St. Anthony's Medical Center; Sean Hill, Linn County Ambulance District; Dr. Elliott Hix, Scotland County Memorial Hospital; Shannon Hobson, Freeman Neoscho; Dr. Eric Hockstad, Research Medical Center; Sara Howard, The Vandiver Group; Lindy Huff, St. Luke's Hospital; Lisa Hutchison, St. John's Regional Health Center; Stacey Jett, Boone Hospital; Leeann Johnson, Staff for Life Helicopter; Freida Juliano, Hannibal Regional Hospital; Melissa Kaufman, Audrain Medical Center; Mike Kendrick, Des Peres Hospital; Daniel Kernebeck, St. Louis University Hospital, Shelleen King, St. Luke's Brain and Stroke Institute; Dr. George Kichura, St. John's Mercy Heart & Vascular; Mary Ann Kirkpatrick, St. John's Hospital; Mary Kleffner, DHSS; Dr. Michael Klevens, St. Luke's Hospital; Brenda Knight, Putnam County Memorial Hospital; Ken Koch, St. Charles County Ambulance District; Sherry Kriegshauser, American Heart Association; Carol Lacy, Salem Memorial Hospital; Susan Ladd, Center for Disease Control and Prevention; Michael Lambert, University of Missouri Health Care; Michelle Leassner, Des Peres Hospital; Theresa Lee, Community Hospital; Katie Liberto, Physio- Control; Dr. Michael Lim, Saint Louis University; Nancy Lindner, Boone Hospital Center; Bonnie Linhardt, American Heart Association; Dean Linneman, DHSS; Colin McCoy, St. Louis Fire Department; Bryant McNally, Missouri Hospital Association; Deborah Markenson, DHSS; Dr. Steve Marso, Cardiovascular Consultants; Chris Medlin, Capital Region Medical Center; Bill Meeker, Laredo Fire Department; Ruby Mehrer, Lifeflight Eagle; Darla Merideth, St. Joseph Hospital West; Taz Meyer, St. Charles County Ambulance District; Eric Mills, University Hospital Ambulance Service; Sharon Monical, Missouri Baptist Medical Center; Nancy Nahlik, Missouri Baptist Medical Center; Greg Natsch, DHSS; Carol Nierling, University of Missouri Hospital and Clinic; Tony Nunn, St. Luke's Hospital of Kansas City; Sarah O'Leary, Center for Disease Control and Prevention; Peggy Parks, Northeast Regional Medical Center; William Pearman, Chariton County Ambulance District; Marie Peoples, DHSS; Joe Piskulic, Jefferson Memorial Hospital; Debbie Playter, Audrain Medical Center; Regine Politte, Jefferson Regional Medical Center; Sharon Pulver, St. Joseph Health Center; Phil Renner, Pike County Memorial Hospital; Dr. Danelle Richards, St. John's Hospital-Lebanon; Lisa Riggs, St. Luke's Health System; Connie Roberts, Putnam County Memorial Hospital; Dr. John Russell, Cape County Private Ambulance Service; Jack Ryan, Philips Healthcare; Wayne Sanders, West County EMS & Fire Protection District; Twany Sandifer, Capital Region Medical Center; Nancy Schuenemeyer, Boone Hospital Center; Chris Schulze, CoxHealth; Barb Seagrass, Des Peres Hospital; Heather Seemann, SSM St. Joseph Hospital of Kirkwood; Dr. Niranjan Singh, University of Missouri School of Medicine; Sondra Solomon, Barnes-Jewish Hospital; Andrew Spain, University of Missouri Hospital and Clinics; Edward Spain, St. John's Regional Health Center; Mary Spencer, Barnes Jewish Hospital; Debby Sprandel, St. Francis Medical Center; David Stagner, St. Francis Medical Center;

Chad Staley, Montgomery County Ambulance District; Mickey Stout, St. John's Hospital – Lebanon; Debbie Summers, St. Luke's Brain and Stroke Institute; Dr. Charles Tillman, Audrain Medical Center; Kathy Vickery, Southeast Missouri Hospital; Phyllis Vos, Research Medical Center; Myrna Ward, Southeast Missouri Hospital; Jim Waring, Wheeler Heart and Vascular Center, Terri Waters, The Vandiver Group; Jeff Wilson, North Kansas City Hospital; Steve Woods, Des Peres Hospital; Monroe Yancie, St. Louis Fire Department; and Beverly Smith, DHSS.

General Information

A total of 130 people attended the fifth meeting of the Time Critical Diagnosis (TCD) Stroke and STEMI System implementation process. Dr. Muzaffar launched the meeting with an overview of the day's objectives and review of the work completed to-date. In the next several months, as the work on the stroke and STEMI center criteria and regulations and out-of-hospital resources is completed, work groups will be transitioning to the professional and public education and quality assurance tasks.

It is important for all work groups to maximize on advantages offered through a **system approach**. Each group should look for new insights and approaches to their tasks that are possible when the all of the agencies within the system work in a collaborative and integrated manner rather than from a single agency perspective. Literature documents that system approaches lead to a decrease in times for delivery of definitive care, not only from the time the patient enters the doors of the hospital but also from the time symptom onset is first noted.

Highlights from the **TCD Trauma Task Force** were shared by Dr. Muzaffar. This task force has worked on the structure and function of the regional committees; reviewing proposed regulations to create an additional trauma center designation at the level IV; updating helicopter early launch, triage and transfer protocols; identifying strategies to increase use of on- and off-line medical control; and establishing a statewide classification scheme to create core standards and consistency.

Sarah O'Leary from the **Centers for Disease Control and Prevention (CDC)** provided an update on CDC's vision and mission for the states' prevention and control efforts for stroke and heart disease. The Missouri Heart Disease and Stroke Prevention Program, funded by CDC, has been an integral partner at DHSS supporting the TCD efforts.

Kelly Ferrara reported on plans have been made by The Vandiver Group with funding from the Missouri Foundation for Health to host **site visits for legislators** to highlight the work being done by the work groups to expand the TCD system. Tentatively four visits have been planned at this time.

Out-of-Hospital Group

The final drafts of the **protocols** for stroke and dispatch were distributed and briefly discussed. Attachments 1 and 2 reflect the most up-to-date versions of these protocols with the key changes suggested at this meeting noted below.

Dispatch:

- The wording was modified regarding the importance of Emergency Medical Dispatch (EMD) agencies using certified personnel and an EMD system that is nationally recognized.
- An air ambulance should be considered when the dispatch call is received if needed to transport the patient within the recommended time window to the appropriate facility.

Stroke:

- Additional detail added on airway oxygenation protocol.
- Recommend the use of the Cincinnati Prehospital Stroke Scale as basic stroke exam standard in the field. It was also recommended that an expanded stroke exam be conducted if time and patient condition allow.

The group reviewed **equipment and technology guidelines** for Emergency Medical Services (EMS) to support care of stroke and STEMI patients. The recommendation was reviewed from the task force report:

The TCD system out-of-hospital providers have equipment and technology that is up to date, compatible and links between EMS and hospital services, and supports accurate patient assessment and recognition of stroke and STEMI symptoms.

Recommendations for equipment and technology guidelines:

- All Advanced Life Support (ALS) and Basic Life Support (BLS) services have the ability to acquire and transmit a 12-lead ECG.
- All services have communication technology and hardware to transmit ECG to receiving facilities.
- All receiving facilities must have appropriate technology to accept transmitted ECG.
- Telemedicine technology should be considered as an option.

Professional education was also discussed by the out-of-hospital work group. The recommendation from the task force report stated:

The TCD system supports training and continuing education for out-of-hospital providers (EMD, EMS, transport personnel) to obtain needed competencies and improve current practices for stroke and STEMI care.

Recommendations for professional education for out-of-hospital personnel:

- Teach the following:
  - Principles of TCD.
  - Importance of early intervention for TCD patients for all disciplines. Recommended that this be done in multidisciplinary group.
  - ECG Indications for 12-lead and 12-lead placement, interpretation and recognition of STEMI.
  - Assessment and management of the STEMI patient.
  - Assessment and management of the stroke patient, including the Cincinnati Stroke Scale.
- Document competencies in all areas.
- Conduct an annual review of new information on assessment and management of TCD conditions and update the training and competencies accordingly.
- Identify priority areas for continuing education based on the quality improvement findings.

Ken Koch shared information that he had received regarding the recommendation that the group should consider expanding 12-lead to 15-lead ECG which is being recommended for assessment of STEMI. This is an issue for discussion with the STEMI group. Through this discussion, the group reinforced the importance of regularly evaluating current best practices and updating training accordingly.

Ruby Mehr presented information about the **Helicopter Early Launch Process (HELP)** which is defined as the request for an air ambulance response prior to EMS arrival on the scene. The State Advisory Committee (SAC) for EMS established an Air Ambulance Subcommittee that compiled guidelines for HELP. These guidelines were developed for use by agencies that incorporate early launch into their protocols.

Ruby shared the PowerPoint presentation that the subcommittee compiled to explain the guidelines. HELP should be considered when ground EMS is greater than 20 minutes from the patient and meets one of the criteria outlined in the guidelines. These criteria fit into three categories which include trauma, burn and medical patients. Suspected stroke and STEMI patients are included in the medical patient category. The guidelines also stated that an air ambulance should be considered when it will assist the TCD patient arrive at the appropriate facility during the time window specific to the disease.

The group discussed level IV centers and concluded that suspected stroke and STEMI patients would not be transferred to a level IV center. The group also reviewed the time frame for making the determination regarding the appropriate facility to which the patient who is having a stroke or STEMI should be taken.

Stroke Work Group

Education Requirements

At the January 6, 2009 meeting, the group standardized the Level I and Level II education requirements (number of hours) for Emergency Department (ED) personnel and Intensive Care Unit (ICU) nurses, so that the annual requirements could be combined with other TCD education requirements. At this meeting, the group focused on the **content** of the education with agreement on the following points:

- National Institutes of Health (NIH) certification should be required for medical personnel who provide care for stroke patients. Certification requirements will vary depending on the stroke center level.
    - Level 4 – only ED personnel are required to be certified.
    - Level 3 – All ED nurses and physicians, and ICU staff are required to be certified.
    - Level 2 – Core stroke team/stroke unit as defined by the Joint Commission, and ICU staff are required to be certified.
    - Level I – Same as Level 2 plus interventional staff are required to be certified.
- A timeframe should be designated, such as "By 2012, all required personnel must be certified."
- A TCD education plan should be developed and materials (e.g., informational DVD or booklet) made available to all hospitals. Prepare presentations for different center levels that includes an overview of what TCD is, what level your facility is and what that means, what to expect when a transferred patient is received from a lower level, etc.
- Put video and other TCD educational tools on 360/365 web site, add links to certification materials on NIH and American Heart Association sites. Ask medical associations to link to 360/365 site.
- Insert TCD information into packets that mail out State Board of Nursing renewal forms.

Inter-facility Transfer Protocols

Eddie Spain facilitated discussion on protocols to transfer stroke patients from one facility to another. The protocols addressed issues for the both non tPA and

FDA-approved stroke lytics at all levels of centers. Attachments 3 through 8 reflect the recommendations of the work group for hospital transfers.

Stroke Regulations

The stroke regulation review was continued from the January meeting. See attachment 9 for the changes that were made.

Discussions prompted review of the different levels of stroke center designation. The group recommends four levels of centers. Bonnie Linhardt stated that the American Heart Association would not support Level IV centers. It was recommended that before the regulations for stroke and STEM are final that the groups compare the different center levels, identify center differences and similarities and align where appropriate.

STEMI Work Group

The group reviewed the STEMI Center designation template, beginning with VII, Personnel Education and Credentials (Attachment 10). The comments that were made on the various sections are included below.

VII. Personnel Education and Credentials.

- It was decided to change this title to Annual Core Competencies.
- The group recommends that training competencies be included but did not have specifics at this meeting.
- Suggested annual acute coronary syndrome course with several components—including how to read the 12 lead ECG, the need for post Percutaneous coronary intervention (PCI) care, identifying major dysrythmia, etc.—would meet part of this training need.
- Will table specifics and refer to professional education committee to address.
- It was suggested that some categories (e.g., telemetry) be added to each staff.
- (2)Medical Director continued. Someone asked what does "ACS-related CEUs" mean? There is no such designation for ACS CEUs.
- Another member remarked that the trauma system currently allows monitoring of CEUs for appropriateness. Practitioners keep a list of topics to document that an adequate number of their CEUs are relevant to their area of expertise and meet requirements.
- A Critical Access Hospitals (CAH) participant stated that they want to be able to participate in the system but aren't able to meet the staffing recommendations for Level III centers. It was further stated that sometimes lytics will be necessary, for example, when the patient is too far from a PCI Center and time is limited. It was

acknowledged that this is a concern. Later the group voted to expand the levels of centers from three to four.
- (3) ED RN credentialing was moved to #1 with the other RN annual core competencies.
- (4) ED core competencies were expanded to include advanced practice providers such as Physician Assistants, etc.
- (6) STEMI Program Manager – needs to be able to oversee quality improvement functions, such as better ways of doing programs to be more effective and establishing a formal QI program related to STEMI.
- (7) Intervention Cardiologists – there was agreement that they should have experience conducting at least 75+ PCI procedures/year.
- There was discussion on education and training needs of other front line staff, such as secretaries who need to know signs and symptoms of a heart attack, etc. Will table this until further discussion on professional education.

VIII – Community Education.
- For public education, the group wants better outcomes but recognize the challenge of changing the public's behaviors. Public education is huge and beyond the scope of this metric; however, the designated centers, Public Education Committee, and State can play a role.
- Messages need to be consistent across the state (a branded program) and formulated based on population needs and demographics.
- (3) Cardiology outreach was changed to "point of access cardiology services outreach program" and was moved to II. (1) c.

IX. Research
- Research is a very broad concept. Level I centers must do research and the requirements were clarified. The research requirement parallels the trauma center requirements for Level Is.
- (1) General requirement included for the STEMI medical director.
- (2) The group voted 26 to 7 to keep the specific examples of research listed.

X. Regional Committee Participation

XI. Performance Metrics
- Discussion focused on clarification of what serves as the denominator for the different measures. It will be important to clearly state the variables in the performance metrics.
- It was recommended that the door to balloon time be based on first medical contact and not on arrival at the facility.
- The metrics will be broken out into three separate ones.
- The group will come back to items no. 2 patient presentation and no. 3 lytics within 30 minutes, at a later time.

- (9) Quality vs. EMS' decision on which place to go will be left for protocol development.
- (10) Risk adjusted mortality will be for levels I – III for further discussion when get data.

XII. Financing

- Want reimbursement to mirror trauma system approach, i.e., if patient's condition warrants taking to designated center outside of health plan coverage, then health plan provides reimbursement for this situation.
- Want to work toward adequate financing of agencies and facilities within TCD STEMI system.

Level IV Centers-STEMI

CAHs expressed concern that the current number of center levels excludes their facilities from being part of the system as a Level III Center because most could not meet the requirement to have an in-house (IH) physician on a 24 hour/7 days a week basis. Discussion centered on whether this could be modified to allow those facilities to be immediately available (IA) or promptly available (PA). There was quite a bit of discussion of whether criteria for Level III centers should be modified so CAHs could qualify or if there was a need to add a Level IV center for STEMI care. A comment was made that smoking and access are two of Missouri's biggest problems contributing to poor outcomes for MI, so we don't want to exclude CAHs (access issue). CAHs have varying capacity. There are advantages for CAHs becoming Level IV Centers because it would create a more inclusive system that would reinforce quality standards, expand data reporting on a statewide basis, and expand public education efforts. Care at the Level IVs would be protocol driven. STEMI patients would be walk-ins for transfer if time permits; or if not, lytics could be given.

It was decided that Level IV centers will be added. This enables eligible CAHs the opportunity to pursue the Level Ill or IV designation and to be a part of the system. The differences between the III and IV level as discussed are detailed below:

Level 3

- 24/7 Emergency Department physician in-house.
- Lytics centers.
- Best standard of care for lytics.
- Specific transfer agreements for patients who fail reperfusion.

Level 4

- Transferring facility.
- 24/7 physician coverage immediately available (within 20 minutes).
- Centers with limited capacity to treat. May provide lytics then ship.

- Shares responsibility for performance at this level and assigns attribution for improving as this is a reportable component.

STEMI and Out-of-Hospital Work Groups

The two work groups met and began discussion on the EMS protocol for care of STEMI patients. The protocol currently under review is included as attachment 11.

Meeting Summaries

STEMI by Dr. George Kichura

- STEMI Center Criteria framework review completed.
- Expanded from 3 levels to 4 levels of centers and that was considered a major milestone. Helped close gaps and address role of rural hospitals within the system.
- Several criteria will require additional detailed discussion, e.g., quality measures-need to look at those that are system-wide.
- Next meeting:
  - Finish center criteria discussions;
  - Will identify those to represent group on the regulation writing group.
  - Prepare for discussions on professional and public education.

Out-of-Hospital by Ken Koch

- Completed dispatch and stroke protocols. Expect that stroke team will have some refinements to add.
- Began discussion of STEMI protocol with STEMI work group.
- Recommendations compiled for equipment and technology guidelines for the new system. Differences were acknowledged in both rural and urban areas regarding how technology is a friend or enemy to this process.

Stroke by Eddie Spain

- Transfer protocols are complete for levels II, III and IV.
- Continued work on rules and regulations. Greg Natch reported that added definition of what this multi-disciplinary team would do and reviewed the requirements of the medical director.
- Appreciate the partnerships being built between the hospital and out-of-hospital providers.
- Professional education requirements defined for all professionals involved. Started with NIH stroke scale for hospital and linked to Joint Commission requirements for each level. These requirements will need to be introduced in phases. Want to use professional organizations for outreach.

Process update by Deborah Markenson

- Each work groups' products will be formatted and compiled into a compendium of resources for final reviews by the implementation work groups. These materials will serve as resources for facilities wanting to become designated center and hospital and out-of-hospital providers. Want to have consistent look for the resources that will support the rules and regulation implementation.
- Six meetings will be held regionally this summer. It is anticipated that draft proposed regulations will be presented for initial and broad public feedback. The regional meetings will be planned based on the current EMS regions. Dates and further information will be coming out to all in the future.

ATTACHMENT 1

Time Critical Diagnosis—Stroke and STEMI System Implementation

Meeting Five, February, 10 2009

TIME CRITICAL DIAGNOSIS DISPATCH PROTOCOL

DISTRIBUTION: All EMS Services.

PURPOSE: To outline the dispatch protocol for all time critical diagnosis patients.

PROTOCOL

1. All emergency medical dispatch agencies shall be certified and have an emergency medical dispatch system (EMDRS) used by nationally recognized EMD certified Emergency Medical Dispatchers.

2. All EMDRS protocols used by emergency medical dispatch agencies must be approved by the EMS Service Medical Director to assure compliance with national standards. Any EMDRS approved by the EMD medical director, including its questions, instructions, codes, and protocols, shall be used as a whole rather than piecemeal.

3. The approved EMDRS shall be used for every request for medical assistance.

4. Each EMD shall follow the questions and decision-making processes within their EMDRS in compliance to the written policies and procedures of their EMD agency as approved by the EMS Service.

5. Each EMD shall provide dispatch life support (including pre-arrival instructions) in compliance to the written text or scripts and other processes within the approved EMDRS.

6. Each EMD agency shall have in place EMS Service approved policies and procedures for the safe and effective use of its approved EMDRS.

7. An air ambulance should be considered when it will assist the Time Critical Diagnosis patient in arriving at the appropriate facility during the time window specific to the disease.

ATTACHMENT 2

Time Critical Diagnosis—Stroke and STEMI System Implementation

Meeting Five, February, 10 2009

STROKE PROTOCOL

DISTRIBUTION: All prehospital operations personnel.

PURPOSE: To outline the treatment guidelines regarding patients experiencing a suspected stroke. Stroke should be treated as an emergency.

ON SCENE

1. ABCs. Maintain oxygen saturation at a minimum of 93%. If oxygen saturation falls below 93%, administer low flow oxygen at 2-4 LPM. Do not routinely administer high flow oxygen to stroke patients. If the patient has shortness of breath, oxygen saturation less than 93%, or decreased level of consciousness, increase oxygen as needed.

2. Obtain blood glucose level. Treat only if less than 50 mg/dl.

3. Obtain vital signs including 12-lead ECG and a brief history (last time seen normal or without symptoms). Make sure to get a phone number where someone knowledgeable of the patient's current condition and health history can be contacted immediately (preferably a cell phone).

4. Perform a basic stroke exam using the Cincinnati Prehospital Stroke Scale. The stroke exam used must be consistent across the region.

5. Do not delay transport. Transport urgently to a stroke center (on scene time of 10 minutes or less). Determine if patient should be transported by ground or air.

NOTE: A stroke center as defined by TCD regulation. Follow regional plan for your area.

If symptom onset is less than 2 hours transport to nearest level I, II or III (treatment needs to start within 3 hours and the hospital will need 1 hour to implement treatment).
If symptom onset is greater than 2 hours or less than 12 hours transport to the highest level stroke center available.

EN ROUTE

1. Contact receiving facility and notify of suspected stroke patient as soon as possible.

2. Establish an IV (preferably 18ga right AC).

3. Perform an expanded stroke exam if time and patient condition will allow (regional

recommendation).

4. Do not treat hypertension without specific approval from the receiving facility.

5. Patient should be transported with head flat, unless risk of aspiration is present.

6. Patient handoff at the hospital should include: patient assessment and condition upon arrival, including time of onset; care provided; changes in condition following treatment and specific immediate family contact information.

ATTACHMENT 3

Time Critical Diagnosis—Stroke and STEMI System Implementation

Meeting Five, February, 10 2009

STROKE INTER-FACILITY TRANSFER PROTOCOL-NON tPA

- Do not delay transport.
- Time last known well/normal
- Neuro exam (signs/symptoms)
- CT – bleed? yes/no
- ABC's (follow Airway/Oxygenation Protocol).
- (add EMT protocol)

- Time transportation was called
- Type of transport (air/ambulance)
- Lab results (glucose) – draw/run
- Exclusions/Inclusions
- Communication - Receiving hospital notified, transfer accepted?
- Strict NPO
- Obtain vital signs
- Copy of records/films, medication list
- Blood pressure management guidelines
- No ASA or Heparin
- Antiemetic
- Contact info
- Current medications
    - Rate
    - ~~tPA~~
- Preferably 2 #18 IV lines or access
    - AC
    - NS
- Protocol guidelines for neurological deterioration en route

ATTACHMENT 4

Time Critical Diagnosis—Stroke and STEMI System Implementation

Meeting Five, February, 10 2009

STROKE LEVEL 2 INTER-FACILITY TRANSFER PROTOCOL- NON tPA

EMS protocol

1. ABC's (follow Airway/Oxygenation Protocol). Maintain oxygen saturation at a minimum of 93%. If oxygen saturation falls below 93%, administer low flow oxygen at 2-4 LPM. Do not routinely administer high flow oxygen to stroke patients. If the patient has shortness of breath, oxygen saturation below 92%, or decreased level of consciousness, increase oxygen as needed.
2. Obtain blood glucose level. Treat only if less than 50 mg/dl.
3. Obtain vital signs including 12-lead ECG and a brief history (last time seen normal or without symptoms). Make sure to get a phone number where someone knowledgeable of the patient's current condition and health history can be contacted immediately (preferably a cell phone).
4. Perform a basic stroke exam.
5. Do not delay transport. Determine if patient should be transported by ground or air.

NOTE: *Follow regional plan for your area. If symptom onset is less than 2 hours transport to nearest Level I center.*

2. Time stamps

1. Last known well (normal)
2. Arrival time
3. CT (when completed and when read/reviewed)

3. Bleed/No bleed

Need CT

4. **Documentation of ~~inclusion/~~exclusion.** [If no exclusion, FDA-approved stroke thrombolytic administered.-use TPA Protocol]

Establish communication with receiving hospital

1. Contact receiving facility and notify of suspected or confirmed stroke patient as soon as possible.
2. Establish 2 PIVs (preferably 18ga AC)

3. Perform an expanded stroke exam if time and patient condition will allow (regional recommendation).
4. Do not treat hypertension without specific approval from the receiving facility
5. Patient should be transported with head flat, unless risk of aspiration is present or hemorrhagic stroke.
6. Patient handoff to receiving facility should include:
    - Patient assessment and condition upon arrival, including time of onset;
    - Care provided;
    - Changes in condition following treatment and specific immediate family contact information.
7. No anti-platelets, no anti-coagulants

ATTACHMENT 5

Time Critical Diagnosis—Stroke and STEMI System Implementation

Meeting Five, February, 10 2009

STROKE LEVEL 2 INTER-FACILITY TRANSFER PROTOCOL- tPA
(FDA approved stroke lytics)

EMS protocol

1. ABC's (follow Airway/Oxygenation Protocol). Maintain oxygen saturation at a minimum of 93%. If oxygen saturation falls below 93%, administer low flow oxygen at 2-4 LPM. Do not routinely administer high flow oxygen to stroke patients. If the patient has shortness of breath, oxygen saturation below 92%, or decreased level of consciousness, increase oxygen as needed.
2. Obtain blood glucose level. Treat only if less than 50 mg/dl.
3. Obtain vital signs including 12-lead ECG and a brief history (last time seen normal or without symptoms). Make sure to get a phone number where someone knowledgeable of the patient's current condition and health history can be contacted immediately (preferably a cell phone).
4. Perform a basic stroke exam.
5. Do not delay transport. Determine if patient should be transported by ground or air.

NOTE: *Follow regional plan for your area. If symptom onset is less than 2 hours transport to nearest Level I center.*

Time stamps

1. Last known well (normal)
2. Arrival time
3. CT (when completed and when read/reviewed)
4. Document and review with transport team: lytics bolus, infusion, and expected completion time(determine tPA protocol/tool kit).
5. Documentation of every 15 minute neuro checks and vital signs.

If condition deteriorating, contact receiving hospital for medical control and discontinue lytics

1. Contact receiving facility and notify of suspected or confirmed stroke patient as soon as possible.
2. Establish 2 PIVs (preferably 18ga AC)
3. Perform an expanded stroke exam if time and patient condition will allow (regional recommendation).

4. Do not treat hypertension without specific approval from the receiving facility.
5. Patient should be transported with head flat, unless risk of aspiration is present or hemorrhagic stroke.
6. Patient handoff to receiving facility should include:
   - Patient assessment and condition upon arrival, including time of onset;
   - Care provided;
   - Changes in condition following treatment and specific immediate family contact information.
7. No anti-platelets, no anti-coagulants.

Time Critical Diagnosis—Stroke and STEMI System Implementation

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STROKE LEVEL 3 INTER-FACILITY TRANSFER PROTOCOL- NON tPA

EMS protocol

1. ABC's (follow Airway/Oxygenation Protocol). Maintain oxygen saturation at a minimum of 93%. If oxygen saturation falls below 93%, administer low flow oxygen at 2-4 LPM. Do not routinely administer high flow oxygen to stroke patients. If the patient has shortness of breath, oxygen saturation below 92%, or decreased level of consciousness, increase oxygen as needed.
2. Obtain blood glucose level. Treat only if less than 50 mg/dl.
3. Obtain vital signs including 12-lead ECG and a brief history (last time seen normal or without symptoms). Make sure to get a phone number where someone knowledgeable of the patient's current condition and health history can be contacted immediately (preferably a cell phone).
4. Perform a basic stroke exam.
5. Do not delay transport. Determine if patient should be transported by ground or air.

NOTE: *Follow regional plan for your area. If symptom onset is less than 2 hours transport to nearest Level I or II center.*

5. **Time stamps**
   1. Last known well (normal)
   2. Arrival time
   3. CT (when completed and when read/reviewed)

6. **Bleed/No bleed**

   Need CT

7. **Documentation of ~~inclusion/~~exclusion.** [If no exclusion, FDA-approved stroke thrombolytic administered- use tPA protocol].

Establish communication with receiving hospital

1. Contact receiving facility and notify of suspected or confirmed stroke patient as soon as possible.
2. Establish 2 PIVs (preferably 18ga AC)

3. Perform an expanded stroke exam if time and patient condition will allow (regional recommendation).
4. Do not treat hypertension without specific approval from the receiving facility
5. Patient should be transported with head flat, unless risk of aspiration is present or hemorrhagic stroke
6. Patient handoff to receiving facility should include:
   - Patient assessment and condition upon arrival, including time of onset;
   - Care provided;
   - Changes in condition following treatment and specific immediate family contact information.
7. No anti-platelets, no anti-coagulants.

ATTACHMENT 7

Time Critical Diagnosis—Stroke and STEMI System Implementation

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STROKE LEVEL 3 INTER-FACILITY TRANSFER PROTOCOL- tPA
(FDS approved stroke lytics)

EMS protocol

- ABC's (follow Airway/Oxygenation Protocol). Maintain oxygen saturation at a minimum of 93%. If oxygen saturation falls below 93%, administer low flow oxygen at 2-4 LPM. Do not routinely administer high flow oxygen to stroke patients. If the patient has shortness of breath, oxygen saturation below 92%, or decreased level of consciousness, increase oxygen as needed.
- Obtain blood glucose level. Treat only if less than 50 mg/dl.
- Obtain vital signs including 12-lead ECG and a brief history (last time seen normal or without symptoms). Make sure to get a phone number where someone knowledgeable of the patient's current condition and health history can be contacted immediately (preferably a cell phone).
- Perform a basic stroke exam.
- Do not delay transport. Determine if patient should be transported by ground or air.

NOTE: *Follow regional plan for your area. If symptom onset is less than 2 hours transport to nearest Level I or II center.*

Time stamps

1. Last known well (normal)
2. Arrival time
3. CT (when completed and when read/reviewed)
4. Document and review with transport team: lytics bolus, infusion, and expected completion time (determine tPA protocol/took kits).
5. Documentation of every 15 minute neuro checks and vital signs.

- If condition deteriorating, contact receiving hospital for medical control and discontinue lytics

1. Contact receiving facility and notify of suspected or confirmed stroke patient as soon as possible.
2. Establish 2 PIVs (preferably 18ga AC)
3. Perform an expanded stroke exam if time and patient condition will allow (regional recommendation).

4. Do not treat hypertension without specific approval from the receiving facility
5. Patient should be transported with head flat, unless risk of aspiration is present or hemorrhagic stroke
6. Patient handoff to receiving facility should include:
    - Patient assessment and condition upon arrival, including time of onset;
    - Care provided;
    - Changes in condition following treatment and specific immediate family contact information.
7. No anti-platelets, no anti-coagulants

ATTACHMENT 8

Time Critical Diagnosis—Stroke and STEMI System Implementation

Meeting Five, February, 10 2009

STROKE LEVEL 4 INTER-FACILITY TRANSFER PROTOCOL- tPA

EMS protocol

1. ABC's (follow Airway/Oxygenation Protocol). Maintain oxygen saturation at a minimum of 93%. If oxygen saturation falls below 93%, administer low flow oxygen at 2-4 LPM. Do not routinely administer high flow oxygen to stroke patients. If the patient has shortness of breath, oxygen saturation below 92%, or decreased level of consciousness, increase oxygen as needed.
2. Obtain blood glucose level. Treat only if less than 50 mg/dl.
3. Obtain vital signs including 12-lead ECG and a brief history (last time seen normal or without symptoms). Make sure to get a phone number where someone knowledgeable of the patient's current condition and health history can be contacted immediately (preferably a cell phone).
4. Perform a basic stroke exam.
5. Do not delay transport. Determine if patient should be transported by ground or air.

NOTE: *Follow regional plan for your area.*

If symptom onset is less than 2 hours, *transport to nearest level I, II or III (treatment needs to start within 3 hours and the hospital will need 1 hour to implement treatment).*
If symptom onset is greater than 2 hours *or less than 12 hours, transport to the highest level stroke center available.*

Time stamps:

1. Last known well (normal)
2. Arrival time

EN ROUTE

1. Contact receiving facility and notify of suspected stroke patient as soon as possible.
2. Establish an IV (follow IV protocol, preferably 18ga right AC)
3. Perform an expanded stroke exam if time and patient condition will allow (regional recommendation).

4. Do not treat hypertension without specific approval from the receiving facility
5. Patient should be transported with head flat, unless risk of aspiration is present
6. Patient handoff at the hospital should include:
    - Patient assessment and condition upon arrival, including time of onset;
    - Care provided;
    - Changes in condition following treatment and specific immediate family contact information.

ATTACHMENT 9

Time Critical Diagnosis—Stroke and STEMI System Implementation

Meeting Five, February, 10 2009

PROPOSED REGULATIONS – STANDARDS FOR STROKE CENTER DESIGNATION

Title 19 - DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30 - Division of Regulation and Licensure
Chapter 40 – Comprehensive Emergency Medical Services Systems Regulations

PROPOSED REGULATIONS

Key

Red-Core issue that links with stroke center criteria in *Stroke Center Designation – Cross Walk*. This document is on Department website under 1/6/09 meeting listing http://www.dhss.mo.gov/TCD_System/Implementation.html

Blue-Changes discussed 1/6/09

Green-Changes discussed 2/10/09

19 CSR 30-40.XXX Standards for Stroke Center Designation.

PURPOSE: This amendment

EDITOR'S NOTE: I-R, II-R, III-R or IV-R after a standard indicates a requirement for level I, II III, or IV stroke center respectively. I-IH, II-IH, III-IH after a standard indicates an in-house requirement for level I, II or III stroke center respectively.
I-IA, II-IA, III-IA, or IV-IA indicates an immediately (20 minutes) available requirement for level I, II, III or IV stroke center respectively. I-PA, II-PA, III-PA or IV-PA indicates a promptly (30 minutes) available requirement for level I, II or III stroke center respectively.

PUBLISHER'S NOTE: The Secretary of State has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome and expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) General Standards for Stroke Center Designation.

(A) The hospital board of directors, administration, medical staff and nursing staff shall demonstrate a commitment to quality stroke care. Methods of demonstrating the commitment shall include, but not be limited to, a board resolution that the hospital governing body agrees to establish policy and procedures for the maintenance of services essential for a stroke center; assure that all stroke patients will receive medical care at the level of the hospital's designation; commit the institution's financial, human and physical resources as needed for the stroke program; and establish a priority admission for the stroke patient to the full services of the institution. (I-R, II-R, III-R IV-R)

3

1. **Stroke centers shall meet national guidelines as established by national organizations including, but not limited to the Joint Commission, the American Stroke Association and the Brain Attack Coalition (I-R, II-R, III-R).**

(B) Stroke centers and participating hospitals shall agree to accept all stroke victims appropriate for the level of care provided at the hospital, regardless of race, sex, creed or ability to pay. (I-R, II-R, III-R, IV-R)

(C) The stroke center ~~hospital~~ shall demonstrate evidence of a stroke program through which professional staff ~~with a Stroke Team that has appropriate experience to~~ maintain skill and proficiency in the care of stroke patients.

1. Such evidence shall include:
   - A. A Stroke Team; (I-R/IA, II-R/IA III-R/IA)
   - B. Meeting continuing education requirements by professional staff; (I-R/IA, II-R/IA III-R/IA IV-R/IA)
   - C. Documented regular attendance of core neurologists and representation from appropriate medical staff, such as neurosurgeons, emergency medicine physicians and anesthesiologists at stroke program performance improvement and patient safety program meetings. Regular attendance shall be defined by each stroke service, but shall be not less than fifty percent (50%) of all meetings; (I-R/IA, II-R/IA, III-R/IA)
   - D. Documentation of continued experience as defined by the stroke Medical Director in management of sufficient numbers of stroke patients to maintain skill levels. The stroke medical director must ensure and document dissemination of information and findings from the peer review meetings to the non-core stroke team members on the stroke call roster; (I-R/IA, II-R/IA) and
   - E. Outcome data on quality of patient care as identified for study by Emergency Medical Services regions. (I-R/IA, II-R/IA III-R/IA IV-R/IA) **1, 2, 5, 6, 7, 11, 19, 21**
2. The designated stroke team shall be available 24 hours per day and consist of, but not limited to:
   - A. Physician experienced in diagnosing and treating cerebrovascular disease
   - B. Another health care professional, (i.e.) nurse, physician's assistant, nurse practitioner. (I-R/IA, II-R/IA III-R/IA IV-R/IA) **2, 6, 7**

END POINT-1/6-09

3. There shall be an expanded multidisciplinary team to develop and evaluate processes and performance improvement for stroke services. The multidisciplinary team shall include but is not limited to a ~~an appropriate~~ representative from hospital administration, emergency medical services, emergency department, medical director, ~~stroke ICU,~~ nursing, pharmacy, CT/radiology, ~~stroke unit~~, rehabilitation, discharge planning, nutritional services and laboratory. Documented regular attendance shall be defined by each center, but shall be not less than fifty percent (50%) of all meetings. (I-R, II-R, III-R) **19, 23**

(D) There shall be a lighted designated helicopter landing area ~~at the stroke center~~ to accommodate incoming medical helicopters. (I-R, II-R, III-R IV-R)

1. The landing area shall serve solely as the receiving and take-off area for medical helicopters and shall be cordoned off at all times from the general public to assure its continual availability and safe operation. (I-R, II-R, III-R ~~IV-R~~)
2. The landing area shall be on the hospital premises no more than three (3) minutes from the emergency room. (I-R, II-R, III-R ~~IV-R~~)

~~(E)~~ The hospital shall appoint a board-certified physician to serve as stroke medical director. The stroke medical director shall have experience in treating stroke patients as evidenced by experience and/or training in at least two of the following~~:, including, but not limited to three of the following:~~

1. Completion of a ~~Board certified neurologist or vascular neurosurgeon with a~~ stroke fellowship;, ~~or neurocritical care fellowship, or vascular neurosurgery fellowship or equivalent experience~~

2. Participation (as an attendee or faculty) in at least 2 regional, national, or international stroke courses or conferences each year;
3. Five (5) or more peer-reviewed publications on stroke;
4. Eight (8) or more continuing medical education (CME) each year in the area of cerebrovascular disease;
5. Other criteria agreed upon by local physicians and hospital administrators.

~~6. Board certified in vascular neurology or neurocritical care~~
~~7. Fellow of the Stroke Council of the AHA~~
~~8. Clinician who diagnoses and treats at least 50 patients with cerebrovascular disease annually or more than 50% of his/her time is dedicated to the care of cerebrovascular patients and/or research on cerebrovascular disease~~
~~9. Clinician with at least 10 peer-reviewed publications dealing with cerebrovascular disease~~

10. Clinician with at least ~~12~~ **8** CME credits each year in areas directly related to cerebrovascular disease to serve as the stroke medical director. (I-R, II-R, III-R) **5 (RECONCILE WITH #4 ABOVE)**

11. There shall be a job description and organization chart depicting the relationship between the stroke medical director and other services. (I-R, II-R, III-R IV-R) **5**

12. The stroke medical director shall be a member of the stroke team call roster. (I-R, II-R, III-R ~~IV-R~~) **5, 7**

13. The stroke medical director shall be responsible for the oversight of the education and training of the medical and nursing staff in stroke care. (I-R, II-R, III-R ~~IV-R~~**) 5, 11**

14. The stroke medical director shall document a minimum average of ~~twelve (12)~~ eight (8) hours of continuing medical education (CME) in cerebrovascular disease every year. (I-R, II-R, III-R ~~IV-R~~) **5, 11 (RECONCILE WITH #4 & 10 ABOVE)**

The stroke medical director shall participate in the stroke center's research and publication projects. (I-R) **5, 18**

END POINT 2/10/09

15. The hospital shall appoint a physician to serve as the stroke medical director. IV-R

(F) There shall be a stroke program manager who is a registered nurse. (I-R, II-R, III-R IV-R) **16**

1. There shall be a job description and organization chart depicting the relationship between the stroke program manager and other services. (I-R, II-R, III-R IV-R)
2. The stroke program manager shall document a minimum average of ten (10) hours of continuing nursing education in cerebrovascular disease every year and attend one national or regional meeting every other year that focuses on some aspect of cerebrovascular disease. (I-R, II-R, III-R IV-R) **11, 16**

(G) All members of the stroke team call roster and emergency medicine physicians shall document a minimum average of eight (8) hours of CME in cerebrovascular disease every year**.** (I-R, II-R, III-R IV-R) **7, 11**

(H) There shall be a specific and well-organized system for rapidly notifying and activating the stroke team to evaluate patients presenting with symptoms suggestive of an acute stroke. (I-R, II-R, III-R IV-R) **2, 7**

(I) Level III or Level IV stroke centers shall have a call roster providing 24 hour a day backup neurology coverage or networking agreement with Level I or Level II stroke center for telephone consult or telemedicine when a neurologist is not available. The

Level III or IV shall have an expedited transfer agreement with the Level I or Level II stroke center. **2, 4, 8**

(J) Rehabilitation services shall be directed by a physician with board certification in physical medicine and rehabilitation or by other properly trained individuals (i.e., neurologist experienced in stroke rehabilitation. (I-R, II-R) **17**

(K) Consults for physical medicine and rehabilitation, physical therapy, occupational therapy, and speech therapy shall be requested and completed within 24 hours of admission. (I-R, II-R) **2, 17**

(L) The hospital shall demonstrate that there is a plan for adequate post-discharge follow-up on stroke patients, including rehabilitation. (I-R, II-R, III-R) **17, 23**

(M) Hospital shall keep stroke team log which contains the following: (I-R, II-R, III-R IV-R)

1. Response times
2. Patient diagnosis
3. Treatment/actions
4. Outcomes (I-R, II-R, III-R IV-R) **1, 7**

(N) A Missouri stroke registry shall be completed on each stroke patient and meets the following criteria: Includes at least one (1) code within the range of the following diagnostic codes as defined in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9)-(CM) XXX-XXX which is incorporated by reference in this rule as published by the Centers for Disease Control and Prevention in 2006 and is available at National Center for Health Statistics, 1600 Clifton Road, Atlanta, Georgia 30333. This rule does not incorporate any subsequent amendments or additions and must include one of the following criteria: hospital admission, or patient transfer out of facility or death resulting from the stroke (independent of hospital admission or hospital transfer status.) The registry shall be submitted electronically in a format defined by the Department of Health and Senior Services. Electronic data shall be submitted quarterly, ninety (90) days after the quarter ends. The stroke registry must be current and complete. A patient log with admission date, patient name, and diagnosis must be available for use during the site review process. Information provided by hospitals on the stroke registry shall be subject to the same confidentiality requirements and procedures contained in section 192.067, RSMo. (I-R, II-R, III-R IV-R) **1**

(O) The hospital shall have a one-call stroke team activation protocol. This protocol will establish the following.

1. The criteria used to rank stroke patients according to time of symptom onset
2. Identifies the persons authorized to notify stroke team members when a suspected stroke patient is en route or has arrived at the stroke center. (I-R, II-R, III-R IV-R) **7, 10**
3. The one-call stroke team activation protocol shall provide for immediate notification and response requirements for stroke team members when a suspected stroke patient is en route to the stroke center. (I-R, II-R, III-R IV-R) **2, 7, 10**

(P) The hospital shall have a plan to notify an organ or tissue procurement organization and cooperate in the procurement of anatomical gifts in accordance with the provisions in section 194.233, RSMo. (I-R, II-R, III-R IV-R)

(Q) There shall be no level III or IV stroke centers designated within fifteen (15) miles of any Missouri level I or II stroke center.

(2) Hospital Organization Standards for Stroke Center Designation.

(A) There shall be a delineation of privileges for the neurologists/neurosurgeons made by the medical staff credentialing committee. (I-R, II-R, III-R) **6, 11**

(B) All members of the stroke team call roster shall comply with the availability and response requirements per the hospital protocol. If not on the hospital premises,

stroke team members who are immediately available shall carry electronic communication devices at all times to permit contact by the hospital and shall respond immediately to a contact by the hospital. (I-R, II-R, III-R, IV-R) **2, 7, 10**

(C) Physicians who are board-certified or board-admissible and who are credentialed by the hospital for stroke care shall be on the stroke center staff and be available as indicated.

1. Neurology—I-R/IA, II-R/IA, III-R/PA **6, 11**
   A. The neurology staffing requirement may be fulfilled by a senior neurology resident credentialed in neurology. **6, 11**
   B. The neurologist shall be immediately available and in attendance with the patient when a neurology resident is fulfilling availability requirements. **2, 6**
2. Neurologic surgery—I-R/IA, II-R/IA **2, 6**
   A. The neurologic surgery staffing requirement may be fulfilled by a surgeon who has been approved by the chief of neurosurgery for care of stroke patients. **6, 11**
   B. The surgeon shall be capable of initiating measures toward stabilizing the patient and performing diagnostic procedures. **6**
   C. In a level I or II stroke center call rosters providing back-up neurosurgeon coverage will be maintained. **6**
3. Emergency medicine—I-R/IH, II-R/IH, III-R/IH IV-R/IA **2, 13**
4. Neuro Endovascular specialist—I-R/IA **6**
5. Diagnostic Radiology—I-R/PA, II-R/PA, III-R/PA **2, 12**
6. Anesthesiology—I-IH, II-R
   A. Anesthesiology staffing requirements may be fulfilled by anesthesiology residents or certified registered nurse anesthetists (CRNA), or anesthesia assistants capable of assessing emergent situations in stroke patients and of providing any indicated treatment including induction of anesthesia. When anesthesiology residents, anesthesia assistants or CRNA's are used to fulfill availability requirements, the staff anesthesiologist on call will be advised and promptly available and present for all operative interventions and emergency airway conditions. The CRNA may proceed with life preserving therapy while the anesthesiologist is en route under the direction of the neurosurgeon, including induction of anesthesia.

(3) Standards for Special Facilities/Resources/Capabilities for Stroke Center Designation.

(A) The hospital shall meet emergency department standards for stroke center designation.

1. The emergency department staffing shall ensure immediate and appropriate care of the stroke patient. (I-R, II-R, III-R IV-R) **13**
   A. The physician director of the emergency department shall be board-certified or board-admissible in emergency medicine. (I-R, II-R) **6, 11, 13**
   B. There shall be a physician trained in stroke care current in cerebrovascular CME in the emergency department twenty-four (24) hours a day (I-R, II-R, III-R) **2, 6, 11, 13**

C. There shall be written protocols defining the relationship of the emergency department physicians to other physician members of the stroke team. (I-R, II-R, III-R, IV-R) **7, 10, 13**

D. All registered nurses assigned to the emergency department shall be credentialed in stroke nursing by the hospital within one (1) year of assignment. (I-R, II-R, III-R IV-R) **11, 13**
E. Registered nurses shall document a minimum of eight (8) hours of stroke-related continuing nursing education per year. (I-R, II-R, III-R IV-R) 11**, 13**
F. The emergency department shall have written care protocols for triage and treatment of acute stroke patients available to ED personnel and should be reviewed and revised annually. (I-R, II-R, III-R, IV-R) 2**, 10, 13**

2. Equipment for resuscitation and life support with age appropriate sizes shall include the following:
   A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, sources of oxygen and mechanical ventilator I-R, II-R, III-R, IV-R (except mechanical ventilator);
   B. Suction devices I-R, II-R, III-R IV-R;
   C. Electrocardiograph, cardiac monitor and defibrillator I-R, II-R, III-R, IV-R;
   D. Central line insertion equipment-I-R, II-R, III-R, IV-R;
   E. All standard intravenous fluids and administration devices including intravenous catheters and IO. I-R, II-R, III-R IV-R;
   F. Sterile surgical sets for procedures standard for the emergency department -I-R, II-R, and III-R;
   G. Gastric lavage equipment -I-R, II-R, III-R IV-R;
   H. Drugs and supplies necessary for emergency care I-R, II-R, III-R, IV-R;
   I. Two-way radio linked with emergency medical service (EMS) vehicles-I-R, II-R, III-R, IV-R;
   J. End-tidal carbon dioxide monitor--I-R, II-R, III-R, IV-R
   K. Temperature control devices for patient, parenteral fluids and blood-I-R, II-R, III-R IV-R;
   L. Rapid infusion system for parenteral infusion-I-R, II-R, III-R, IV-R.
3. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R, III-R, IV-R, IV-R)
4. There shall be CT capability with twenty-four (24) hour coverage by technicians.(I-IH, II-IH, III-IA) 2**, 9, 12**

(B) The hospital shall have a designated stroke ICU for stroke center designation. (I-R. II-R) **15**

1. There shall be a designated stroke medical director for the ICU. (I-R, II-R) **5, 15**
2. A physician who is not the emergency department physician shall be on duty in the ICU or available in-house twenty-four (24) hours a day in a level I stroke center. **2, 6, 15**
3. The minimum registered nurse/patient ratio used shall be one to one (1:1) or one to two (1:2). (I-R, II-R)
4. Registered nurses shall have a minimum of ten (10) hours of stroke-related continuing nursing education per year. (I-R, II-R) **11, 15**
5. There shall be beds for stroke patients or comparable level of care provided until space is available in ICU. (I-R, II-R)
6. Equipment for resuscitation and to provide life support for the stroke patient shall be available for the intensive care unit. This equipment shall include, but not be limited to:
   A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, and a mechanical ventilator (I-R, II-R)
   B. Oxygen source with concentration controls-(I-R, II-R)

C. Cardiac emergency cart, including medications (I-R, II-R)
D. Electrocardiograph, cardiac monitor and defibrillator (I-R, II-R)
E. Electronic pressure monitoring and pulse oximetry (I-R, II-R)
F. End-tidal carbon dioxide monitor and mechanical ventilators (I-R, II-R)
G. Patient weighing devices (I-R, II-R)
H. Drugs, intravenous fluids and supplies (I-R, II-R)
I. Intracranial pressure monitoring devices (I-R, II-R)

7. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R)

(C) The hospital shall meet post-anesthesia recovery room (PAR) standards for stroke center designation. (I-R, II-R)
1. Registered nurses and other essential personnel who are not on duty shall be on call and available within **sixty (60)** minutes. (I-R, II-R)
2. Equipment for resuscitation and to provide life support for the stroke patient shall include, but not be limited to:
A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen and mechanical ventilator-(I-R, II-R)
B. Suction devices (I-R, II-R)
C. Electrocardiograph, cardiac monitor and defibrillator (I-R, II-R)
D. All standard intravenous fluids and administration devices, including intravenous catheters (I-R, II-R)
E. Drugs and supplies necessary for emergency care (I-R, II-R)

(D) The hospital shall have stroke rehabilitation or a written transfer agreement. (I-R, II-R, III-R, IV-R)

(E) Radiological capabilities for stroke center designation including a mechanism for timely interpretation to aid in patient management shall include: **2, 9, 12**
1. Angiography with interventional capability available twenty-four (24) hours a day with a 1 (one) hour maximum response time (I-R, II-R)
2. Resuscitation equipment available to the radiology department-I-R, II-R, III-R;
3. In-house computerized tomography (I-R, II-R, III-R) 9**, 12**
4. Computerized tomography technician (I-IH, II-IH, III-IA) 2**, 9, 12**

(F) There shall be documentation of adequate support services in assisting the patient's family from the time of entry into the facility to the time of discharge. (I-R, II-R, III-R) **23**

(G) The stroke unit of a designated stroke center shall have the following personnel and equipment: (I-R, II-R, III-R) **14**
1. Registered nurses and other essential personnel on duty twenty-four (24) hours a day (I-R, II-R) **2, 14**
2. Equipment for resuscitation and to provide supports for the stroke patient including, but not limited to:
A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator and sources of oxygen (I-R, II-R, III-R)
B. Suction devices (I-R, II-R, III-R)
C. Electrocardiograph, cardiac monitor and defibrillator (I-R, II-R, III-R)
D. All standard intravenous fluids and administration devices and intravenous catheters (I-R, II-R, III-R)
E. Drugs and supplies necessary for emergency care (I-R, II-R, III-R)
3. Documentation that all equipment is checked according to the hospital preventive maintenance schedule (I-R, II-R, III-R)

(H) The operating room personnel, equipment and procedures of a stroke center shall include, but not be limited to:
1. An operating room adequately staffed in-house twenty-four (24) hours a day (I-R, II-R)

2. Equipment including, but not limited to:
   A. Operating microscope-(I-R, II-R);
   B. Thermal control equipment for patient, parenteral fluids and blood (I-R, II-R)
   C. X-ray capability- (I-R, II-R)
   D. Instruments necessary to perform an open craniotomy-(I-R, II-R)
   E. Monitoring equipment-(I-R, II-R)
3. Documentation that all equipment is checked according to the hospital preventive maintenance schedule-I-R, II-R, III-R;

(I) The following clinical laboratory services shall be available twenty-four (24) hours a day: **2, 24**

1. Standard analyses of blood, urine and other body fluids-(I-R, II-R, III-R, IV-R) 24
2. Blood typing and cross-matching—(I-R, II-R, III-R) **24**
3. Coagulation studies—(I-R, II-R, III-R, IV-R) **24**
4. Comprehensive blood bank or access to a community central blood bank and adequate hospital blood storage facilities- (I-R, II-R, III-R) **24**
5. Blood gases and pH determinations- (I-R, II-R, III-R, IV-R) **24**
6. Blood chemistries (I-R, II-R, III-R, IV-R) **24**

(4) Standards for Programs in Performance Improvement Patient Safety Program, Outreach, Public Education and Training for Stroke Center Designation.

(A) There shall be an ongoing performance improvement and patient safety program designed to objectively and systematically monitor, review and evaluate the quality, timeliness and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems. (I-R, II-R, III-R IV-R) **1, 2, 21**

(B) The following additional performance improvement and patient safety measures shall be required:

1. All stroke centers shall collect, trend and electronically report to the Department key data indicators as identified by Department of Health and Senior Services. (I-R, II-R, III-R, IV-R) **1, 21**
2. Regular reviews of all stroke-related deaths—(I-R, II-R, III-R, IV-R) **1, 21**
3. A regular morbidity and mortality review, at least quarterly-(I-R, II-R, III-R, IV-R) **1, 21**
4. A regular multidisciplinary stroke meeting that includes representation of all members of the stroke team, with minutes of the meetings to include attendance, adherence to the stroke protocol and findings-I-R, II-R, III-R, IV-R; **1, 7, 10, 19, 21**
5. Regular reviews of the reports generated by the Department of Health and Senior Services from the Missouri stroke registry (I-R, II-R, III-R, IV-R) **1, 21**
6. Regular reviews of pre-hospital stroke care including inter-facility transfers **(**I-R, II-R, III-R, IV-R) **1, 21**
7. Participation in EMS regional systems of stroke care as established by the Department of Health and Senior Services (I-R, II-R, III-R, IV-R)
8. Stroke patients remaining greater than six (6) hours prior to transfer will be reviewed as a part of the performance improvement and patient safety program. I-R, II-R, III-R, IV-R. **1, 2, 21**

(C) A neurology outreach program shall be established to assure twenty-four (24) hour availability of telephone consultation or telemedicine with physicians in the outlying region. (I-R, II-R) 2**, 6, 8**

(D) A public education program shall be established to promote stroke prevention and signs and symptoms awareness and to resolve problems confronting the

public, medical profession and hospitals regarding optimal care. (I-R, II-R,III-R) **20**

(E) The hospital shall be actively involved in local and regional EMS systems by providing training and clinical resources. (I-R, II-R, III-R)

(F) There shall be a hospital-approved procedure for credentialing nurses in stroke care. (I-R, II-R, III-R, IV-R) **11**

1. All nurses providing care to stroke patients and assigned to the emergency department or ICU shall complete a minimum of sixteen (16) hours of stroke nursing courses to become credentialed in stroke care. (I-R, II-R, III-R, IV-R) **2, 11, 15**
2. The content and format of any stroke nursing courses developed and offered by a hospital shall be developed in cooperation with the stroke medical director. A copy of the course curriculum used shall be filed with the HSL. (I-R, II-R, III-R, IV-R)

(G) A hospital diversion protocol must be maintained in accordance with state regulations. This protocol is designed to allow best resource management within a given area. This protocol must contain a defined performance improvement and patient safety process to review and validate established criteria within that institution. Hospital diversion information must be maintained to include date, length of time and reason for diversion.

(5) Standards for the Programs in Stroke Research for Stroke Center Designation.

(A) The hospital and its staff shall support a research program in stroke as evidenced by any of the following: **3, 18**

1. Publications in peer reviewed journals--I-R; **18**
2. Reports of findings presented at regional or national meetings--I-R; **18**
3. Receipt of grants for study of stroke care--I-R; and **18**
4. Production of evidence based reviews--I-R. **18**

(B) The hospital shall agree to cooperate and participate with the DHSS in conducting epidemiological studies and individual case studies for the purpose of developing stroke prevention programs. (I-R, II-R, III-R, IV-R) **3, 18**

AUTHORITY

**Original authority: 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002 and 190.241, RSMo 1987 amended 1998.*

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions

PRIVATE COST: This proposed amendment will cost private entities

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Kimberly O'Brien, Director, Department of Health and Senior Services, Division of Regulation and Licensure, PO Box 570, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

ATTACHMENT 10

Time Critical Diagnosis—Stroke and STEMI System Implementation

Meeting Five, February, 10 2009

HOSPITAL STEMI WORK GROUP-CRITERIA FOR STEMI CENTER DESIGNATIONS

CRITERIA	LEVEL I	LEVEL II	LEVEL III	LEVEL IV
I. STEMI Center Volumes:				
1. Total number of elective Percutaneous Coronary Interventions (PCI) /year/ center	400	200		
2. ~~75+ PCI procedures/year/physician~~ move to staff req./recommendations	~~x~~	~~x~~		
3. Primary PCI (PPCI)/Year/center	> 49	> 36		
~~4. Annual Hospital STEMI patient volume~~	~~85-90~~	~~60-65~~		
II. STEMI Center Hospital Capabilities:				
1) STEMI Program	X	X	X	
a) STEMI Medical Director-board certified, job description, org chart showing relation to other departments, oversee staffing, assure training CEUs for staff and CMEs/year for physicians,	X	X	X	x
b) STEMI Program Manager (RN or qualified individual)	X	X	X	x
c) STEMI Team				
i. Physician experienced in diagnosing and treating cardiovascular disease and STEMI (available 24/7)	X	X	X	x
ii. Another health care professional credentialed in STEMI as determined by hospital (available 24/7)	X	X	X	x
iii. Cardiology outreach services available to other facilities	X			
d) Representation from hospital administration, EMS, ED, ICU, pharmacy, cardiac cath lab, CVD-MI unit, rehabilitation, discharge planning, laboratory, nutrition services	X	X		
2) Availability of hospital departments/services to support STEMI care				
a) Emergency Department	X	X	X	x
b) Intensive Care Unit	X	X	x	
c) Inpatient areas	X	X	X	
d) General standards for staffing and competencies of these areas	X	X	X	x
e) One-call point of access to cardiology services outreach program for 24-hour phone consults	x	x		

CRITERIA	LEVEL I	LEVEL II	LEVEL III	LEVEL IV
3) **Time Frame** for availability of services (IH = in house; IA = 20 minutes; PA = 30 minutes)				
a) 24/7 Emergency Department with physician access	IH	IH	IH	IA
b) 24/7 CATH Lab, angiography and interventional capabilities available	PA	PA		
c) 24/7 Coronary Artery Bypass Graft (CABG)	PA			
d) Core STEMI Team Members	PA	PA	PA	
e) 24/7 **Clinical Laboratory** to provide necessary testing and results	x	x	x	x
f) **One call activation for cath lab**	x	x		
g) One call access to transfer STEMI			x	x
h) Access to cardiac rehab	x	x	x	
i) 24/7 **Surgical Backup (regs will define specific equip needed)**	x			
III. Hospital protocol for pre-hospital and STEMI Team Communication				
1. EKG, system for communication between hospital and EMS staff 24/7, link to EM system that provides hospital diversion status	x	x	x	x
2. Mechanism in place for activation of Cardiac Cath lab team at time of EMS STEMI identification	x	x	x	x
IV. Hospital protocol for rapid transfer from non-PCI facility (when appropriate)				
1. **Accept all** STEMI transfers	x	x		
2. ~~Formal~~ Written **agreement** with Level I/Level II STEMI Center to transfer and accept complex patients	x	x	x	x
3. A rapid transfer **process** in place with higher level of STEMI care		x	x	x
4. A hospital diversion protocol must be maintained in accordance with state regulations… (In current trauma regulations. This will need to be validated with legal teams and risk managers.)	x	x	x	x
V. Hospital protocol for care and coordination				
1. Agree to accept all STEMI patients appropriate for the level of care provided at the hospital, regardless of race, sex, creed or ability to pay	x	x	x	x

	CRITERIA	LEVEL I	LEVEL II	LEVEL III	LEVEL IV
	2. Staff ~~credentialed~~ core competencies in STEMI (see credential section.)	x	x	x	x
	3. Protocol for cardiac rehabilitation—Phase I is in-house	x	x		
VI.	**Hospital capacity to support STEMI patient discharge transition back to community and/or rehabilitation facility if needed.**				
	1. Arrangement/ discharge plan for the provision of cardiac rehabilitation post discharge—part of discharge documentation. Protocol for discharge transition back to care and oversight by Primary Care Physician (PCP) or rehabilitation facility if needed (coordinate with existing procedures) o Secondary prevention o Discharge planning	x	x		
	2. Arrangement/ discharge plan for the provision of repatriation to community hospital if indicated				
	3. Timely feedback (recommend within 72 hours) for sending and receiving facilities/EMS providers. ~~Call within 24 hours followed with written notice within 72 hours (this is reference to EMS providers)~~	x	x		
VII.	**Annual Core Competencies:**				
	1. RN ~~credentialing~~ annual STEMI core competencies for ED, ICU, Cath Lab and Telemetry	x	x	x	x
	2. STEMI Medical Director CEU hours – 10 ACS-related hours in 3 years	x	x	x	x
	~~3. Emergency Department RN CEUs~~	~~x~~	~~x~~	~~x~~	~~x~~
	4. Annual STEMI core competencies ~~Minimum CEU requirements~~ for ED Physicians and advanced practice providers	x	x	x	x
	5. Annual STEMI core competencies for Cath Lab staff	x	x		
	6. STEMI Program Manager association with formal quality improvement program related to STEMI	X	X	X	x
	7. Interventional Cardiologist (75+ PCI/phys/year recommended)	x	x		
VIII.	**Community Education:**				
	1. Public education program for STEMI signs/symptoms, emergency transport, STEMI treatment and center service availability	x	x	x	
	2. Ability to collect and report data to STEMI registry & DHSS	x	x	x	x

CRITERIA	LEVEL I	LEVEL II	LEVEL III	LEVEL IV
~~3.~~ ~~One-call point of access to cardiology services outreach program for 24-hour phone consults~~ (moved to II.)	x	x		
IX. Research: Pick preferred language:				
1. The STEMI medical director shall participate in the STEMI center's research and publication projects ~~*Institution will conduct or participate in research study that is under auspices of Institutional Review Board oversight either at that facility or cooperative facility.*~~				
2. The hospital and its staff shall support a research program in STEMI as evidenced by any of the following, including but not limited to: a. Publications in a peer review journal b. Reports of findings presented at regional and/or national conferences c. Receipt of grants for study of STEMI care d. Production of evidenced based reviews.				
3. The hospital shall agree to cooperate and participate with the DHSS in conducting epidemiological studies and individual case studies for the purpose of developing STEMI prevention programs.	x	x		x
X. Participate in Quarterly regional STEMI conferences	**x**	**x**		**x**
XI. Performance Metrics:				
1. P~~CI within 60 +/- 30 minutes of arrival (75-80% of time) (need data set to evaluate appropriate x% of time; may need to consider timeframe for this criteria; time is based on first medical contact time. Challenge in view of current data based on D2B time. Must evolve metric to reflect time from symptoms to time to definitive care.)~~	~~X~~			
Device or balloon within 90 ~~+/- 30~~ min from first medical contact ~~facility arrival~~ or field EKG STEMI diagnosis (75% of time)	X			
2. Patient presentation—do different metrics based on whether patient is walk-in, transfer, versus EMS transport, time for EMS transfers from one hospital to higher level when needed. (Starting point for next meeting discussion)				
3. Lytics within 30 minutes of first medical contact or arrival (75-80% of time)		x		x
4. Formal STEMI/AMI CQI process	x	x		x

CRITERIA	LEVEL I	LEVEL II	LEVEL III	LEVEL IV
5. Immediate (define) feedback to the transfer hospital and EMS	x			
6. Competencies for the practitioner, nurse and physician	x	x		x
7. State Registry reporting	x	x		x
8. ACC guidelines/registry	x	x		
9. Quality vs. what for EMS to decide which place to go (…leave for protocols discussion)				
10. Risk adjusted mortality	x	x		x
XII. Financing				
Further discussion needed on reimbursement issues and assurances for adequate financing of agencies and facilities within STEMI-TCD system				

ATTACHMENT 11

Time Critical Diagnosis—Stroke and STEMI System Implementation

Meeting Five, February, 10 2009

STEMI EMS PROTOCOL

DISTRIBUTION: All Prehospital Operations Personnel.
Changes Feb. 10 revised by out of hospital and STEMI group jointly

PURPOSE: To outline the treatment guidelines to be followed for patients presenting with *(need definition)

PROTOCOL

1. Obtain a 12-Lead ECG within 5 minutes of patient contact and transmit as early as possible to the receiving facility. If time permits, obtain serial 12 leads during transport. 15 lead if time permits?

2. ABCs; administer oxygen; obtain vital signs & history; apply ECG and continuously monitor.

3. Decide which STEMI center to transport to and determine if patient should be transported by ground or air.

4. Unless contraindicated, administer 4 chewable baby aspirin (81 mg. each).

5. Begin transport urgently (within 10 minutes) to a STEMI center. In the event the patient develops an unmanageable life-threatening situation while enroute, contact the closest hospital and obtain orders and/or authorization to divert to that facility.

   NOTE: An *appropriate facility offering primary PCI* as defined by TCD regulation.
   Level ? if < ? minutes
   Level ? if > ? minutes but < ? minutes
   (table discussion)

6. Obtain medication and allergy information.

7. Establish IV (preferably in Left arm).

8. If SBP > 140 mmHg and patient is presenting with cardiac type chest pain or discomfort, administer *Nitro* sublingually per regional protocol. If RV infarct identified do not administer nitro. Ask if the patient is taking an ED drug.

Start here at March meeting

9. If BP < 90 mmHg and patient is not in acute pulmonary edema administer a 300 mL fluid challenge.

10. If chest pain is still present administer MORPHINE SULFATE (*Morphine*) in increments of 2-4 mg, titrate to relief of pain.

11. Contact Medical Control for further orders as soon as possible. Examples of possible orders listed below.

12. Patient handoff at the hospital should include: patient assessment and condition upon arrival, including time of onset, copies of 12-lead ECG; care provided; and changes in condition following treatment and specific immediate family contact information.